Product Specification of:

# Medical Oxygen Sensor

## Type: M-16

**Part Number: 470016**

RoHS compliant and SVHC free
Meets the applicable requirements of ISO 80601-2-55
Comes with CE marking, further regulatory registrations available upon request
Produced under EN ISO 13485 Quality Management System

## DOCUMENT PURPOSE

**The purpose of this document is to present the performance specification and key features of the sensor.**

**This document should be used in conjunction with the Operating Manual of the instrument and the Product Safety Data Sheet of the sensor.**




## KEY FEATURES

**Long-life galvanic gas sensor with high signal stability at low cross sensitivity to anesthesia gases combined with superior linearity over the entire measurement range.**

| High Signal Stability | Superior Linearity | Wide Measurement Range | Long Lifetime |
|---|---|---|---|



**IT Dr. Gambert GmbH** .: Hinter dem Chor 21 .: 23966 Wismar .: Germany
Phone: +49 (0)3841 220 050 .: Fax: +49 (0)3841 220 052 2 .: E-Mail: info@itg-wismar.de **www.itg-wismar.de**

## TECHNICAL SPECIFICATIONS

**Important Note:** All characteristics are based on conditions at 25 °C, 50 %rH, 1013 hPa and a gas flow of > 2.5 $L_S$/min. For sensor performance data under other conditions, contact ITG.

While ITG may provide information or engineering support for its products through ITG personnel, literature and website, it is the customers sole responsibility to determine the suitability of the product(s) for the customer requirements and applications.

### MEASUREMENT

| | | |
|---|---|---|
| **Operating Principle:** | Partial pressure electrochemical cell | |
| **Measurement Range:** | 0 ... 100 Vol.% $O_2$ | |
| **Initial Output Signal:** | 9.5 ... 16.0 mV | at dry ambient air |
| **Response Time t90:** | < 12 s | |
| **Signal Drift (long-term):** | ≤ ± 1 Vol.% $O_2$ / month | at ambient air |
| **Linearity Error:** | ≤ ± 3 % | at 100 Vol.% $O_2$ applied for 5 min |
| **Zero Signal Offset:** | ≤ 0.3 Vol.% $O_2$ | at 100 Vol.% $N_2$ applied for 5 min |
| **Repeatability Error:** | ≤ ± 1 Vol.% $O_2$ | at 100 Vol.% $O_2$ applied for 5 min |
| **Influence of Gas Humidity:** | - 0.03 % of signal per %rH | |
| **Signal Temperature Compensation:** | NTC on sensor PCB | |
| **Cross-Sensitivity:** | according to DIN EN ISO 80601-2-55 | |

### ELECTRICAL

| | | |
|---|---|---|
| **Electrical Connector:** | 3-Pin Molex | |
| **Recommended Load Resistor:** | ≥ 10 kOhm | |

### MECHANICAL

| | | |
|---|---|---|
| **Weight:** | ≤ 26 g | |
| **Material in Contact with Media:** | PA, PPS, PTFE, Stainless Steel, NBR | |
| **Gas Connector:** | fits for M16x1 DIN 13 or 5/8-24 UNEF | |

### ENVIRONMENTAL

| | | |
|---|---|---|
| **Operating Temperature Range:** | 10 ... 40 °C | |
| **Ambient Pressure Range:** | 700 ... 1250 hPa | hPa |
| **Ambient Humidity Range:** | up to 100 %rH | non-condensing |

### LIFETIME including shelf life

| | | |
|---|---|---|
| **Expected Operating Life:** | 1 ... 6 years | can vary significantly by application<br>read Lifetime info box on next page |
| **Nominal Sensor Life:** | 750 000 Vol.%h $O_2$ | at ambient air, depending on application |



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## STORAGE CONDITIONS IN UNOPENED ORIGINAL PACKAGE

| | | |
|---|---|---|
| Ambient Temperature Range: | 0 ... 40 °C | -- |
| | 15 ... 25 °C | recommended |
| | -20 ... 50 °C | maximum (≤ 10 h) |
| Ambient Pressure Range: | 700 ... 1250 hPa | |
| Ambient Humidity Range: | 50 ... 100 %rH | recommended, non-condensing |
| | 0 ... 30 %rH | maximum one week |

## RELATED PRODUCTS

| Product | Part Number | Other Specifics |
|---|---|---|
| $O_2$ Sensor M-16 | 47 00 16 | -- |
| $O_2$ Sensor M-16T | 47 01 16 | translucent housing |
| $O_2$ Sensor M-16HT | 47 06 16 | designed for high temperature range |
| $O_2$ Sensor M-16HTT | 47 02 16 | translucent housing, designed for high temperature range |

## Lifetime and Shelf Life

Temperature and humidity are two of the most essential environmental factors. Electrochemical gas sensors contain a liquid electrolyte that may evaporate over time. This process speeds up in hot, dry conditions and with increased gas flow. On the other side, low temperatures can slow down a sensor's reaction or lead to inaccurate zero readings.

Humidity presents another challenge. When moisture condenses at the gas inlet, it can impact measurement precision or potentially lead to corrosion. Abrupt changes in temperature or being in humid settings, such as coastal or marine applications, increase the risk of signal drift and malfunction.

Dusty air, vapors from cleaning agents, emissions from batteries, industrial pollutants, etc. can affect sensor performance over time. These pollutants might not cause immediate malfunction but can gradually reduce sensor performance.

Sensors keep aging even when the devices are switched off. When a device is kept in uncontrolled ambient conditions, like inside a hot truck cab or on a dusty shelf, its future performance is at risk.

Devices should ideally be kept in temperature-controlled, clean, and dry environments. Even when the device is not in operation, it may come into contact with vaporized substances or changes in the environment that impact its effectiveness. Inadequate storage methods are among the most neglected reasons for premature sensor malfunction.

To maximize the sensor`s operating time, transport and storage times should be kept as short as possible (ideally < 6 months).

## Installation in Device

A gas tight sealing is ensured when the sensor is screwed in hand-tight. Do not use any mechanical tools to install the sensor. Using excessive force may damage the sensor.

Optimal mounting position of the sensor is when the gas sensing area faces downwards. A horizontal position is acceptable. It is not recommended to use the sensor with the gas sensing area facing upward.

Connection should be made via recommended electrical and mechanical connectors only. The specified load resistance must be taken into account. Soldering the sensor will damage it and void the warranty. Please contact ITG for further information.

Since temperature has an influence on the output signal it is not advisable to place any heat or vibration sources (i.e. electric-pumps or valves, coolers, etc.) in close proximity to the cell.

Avoid proximity of the cell to any EMC radiating units as those emit frequencies which might interfere with the sensor`s electrical connection and connecting cable.



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## Cleaning and Disinfection

The sensor outer housing can be cleaned with a dry wipe. Do not wipe the sensor`s gas entrance side. Do not use any chemical disinfectant or sanitizer on the sensor.

## Poisoning

ITG sensors are designed to operate in a wide range of environments. For optimal sensor lifetime and performance it is important that exposure to high concentrations of solvent vapors is avoided during storage, installation into instruments and operation of the sensor.

Do not use adhesives directly on or near the sensor as the solvents may cause stress corrosion on the plastic parts.

## Intended Use

The electrochemical oxygen sensors for use in medical technology are used as accessories with a limited shelf life exclusively in conjunction with other medical products (ventilators, incubators, anesthesia machines, portable oxygen monitors, oxygen therapy devices and gas mixing units) so that they can fulfill the manufacturer`s intended purpose.

The oxygen sensors measure the oxygen partial pressure in gas mixtures.

Commissioning and use is carried out exclusively by expert clinic or service personnel. Direct contact with these items occurs during installation or maintenance by trained personnel.

## Stabilization Time

When installing a new sensor refer to the instrument manual for stabilization time before calibration.

If not specified otherwise wait at least 15 minutes to ensure that the sensor has stabilized in the instrument.

## Calibration Interval

ITG sensors are designed to have minimal signal drift over their functional lifetime. For optimal performance and maximum measurement accuracy however they should be calibrated before each use.

## If the Sensor is dropped

If a sensor is dropped, please check for visible mechanical damage of the sensor or if the sensor is leaking electrolyte. If this is the case, do not try to install the sensor into the device. Take safety precautions and immediately dispose the cell.

If the sensor shows no visible damage it should be placed in quarantine for at least 24 hours. Afterwards a follow-up check made by a two point calibration should be done.

## RFI/EMI Susceptibility

ITG sensors contain metal parts and might be susceptible to RFI or EMI. Before use in MRI environments please contact ITG for further information.

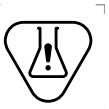
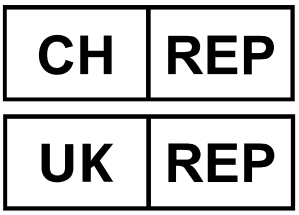
## Disposal

At the end of the sensors lifetime the sensor should not be disposed of in normal public waste as it may contain hazardous materials and caustic electrolyte (for more information refer to the PSDS). Please contact your local authorities for environmental legislation to relevant local waste disposal.



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## Description of Pictograms

| | |
|---|---|
|  | Manufacturer |
|  | Medical device |
|  | Model number<br>Customer sensor type / Customer article number |
|  | Sensor part number of the manufacturer<br>ITG sensor type / ITG article number |
|  | Serial number |
|  | Contains hazardous substances |
|  | Indicates the temperature limits to which the medical device can be safely exposed |
|  | Expiration Date (DD-MM-YYYY) |
|  | Responsible representative in the territory |
|  | Federal law restricts this device to sale by or on the order of a licensed practitioner (U.S. only) |
|  | CE Marking with certifying notified body number |

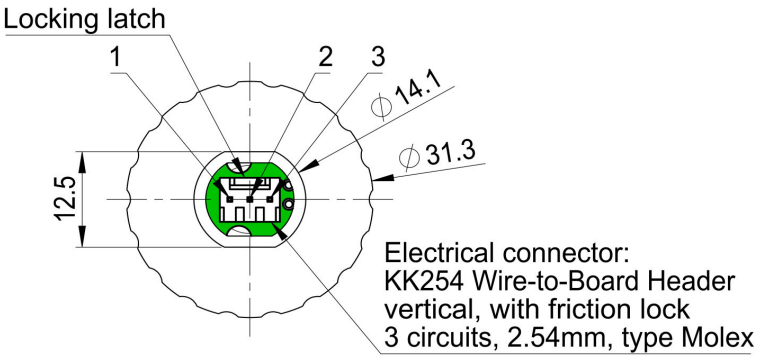


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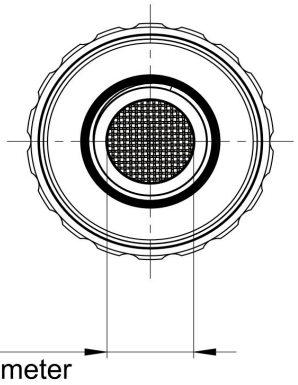
## TECHNICAL DRAWING

| Sensor | ITG Part number | Color | | | Electrical pin assignment | | |
|---|---|---|---|---|---|---|---|
| | | Cap | Housing | Threaded ring | Pin 1 | Pin 2 | Pin 3 |
| M-16 | 470016 | white | white | white | minus (-) | minus (-) | plus (+) |

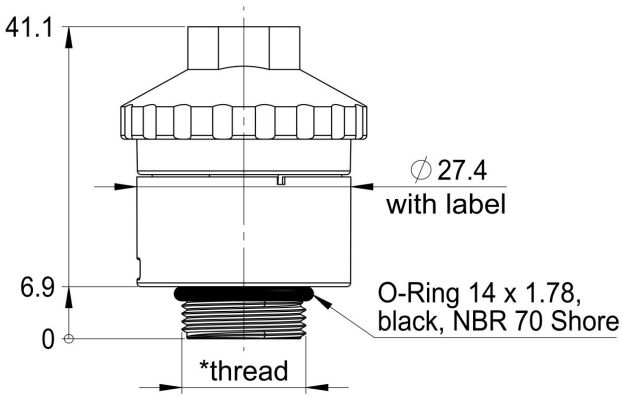
**Top view**




**Bottom view**




**Front view**




[* thread is compatible with DIN 13 M16x1 and UNEF 5/8-24]

Dimension unit: mm
Dimension tolerances: linear ±0.5 mm , diameter ±0.3 mm



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